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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,963	09/19/2000	Kevin W. Anderson	M 6560 OS/OAPT	5388

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COGNIS CORPORATION
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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/22/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,963

Applicant(s)

WENZEL ET AL.

Examiner

DR. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/05/2002 (Paper Number 20).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 14-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' appeal brief filed 06/05/2002 (Paper Number 20) is acknowledged and entered.
2. Applicants' petition filed 16 October, 2001 as paper number 17 for review of the restriction requirement set forth on April 18, 2001 as paper number 6 under the provisions of 37 CFR 1.144 has been granted in part in the Communication dated April 19, 2002 as paper number 18 from the Director, Technology Center 1600. Consequently, Groups I and II as set forth in the restriction requirement dated April 18, 2001 have now been rejoined. As a result the claims elected for prosecution by the applicants in Amendment filed 8 May 2001 as paper Number 8 now encompasses Claims 1-13.
3. In view of the decision on the petition, PROSECUTION IS HEREBY REOPENED. A New ground of rejection is set forth below. To avoid abandonment of the application, appellant must exercise one of the following two options:
file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
request reinstatement of the appeal.
If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).
4. Claims 1-28 are pending.
5. Claims 4-5, 8-9 and 14-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected claims, there being no allowable generic or linking claim.
6. Claims 1-3, 6-7 and 10-13 are examined on the merits.

Claim Rejections - 35 U.S.C. § 112

7. Following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-3, 6-7 and 10-12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The phrase, "substantially free of particulate material and bacteria" in Claim 1(e) renders that Claim indefinite. It is not clear whether this phrase means that the biotin should be free of any extraneous materials and contaminants, or the claimed culture medium comprising the said biotin should be free of particles. Applicants are required to clarify the phrase "substantially free of particulate material and bacteria."

Claim Rejections - 35 U.S.C. § 103

9. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

11. Claims 1-3, 6-7 and 10-13 are rejected under 35 U.S.C. § 103 (a) as obvious over Shirai et al (U.S. Patent 5,618,708) in view of Pelczar et al (Microbiology, 1977, McGraw Hill Book Company, Pages 110-111 and 428-429).

Claims recite a culture medium comprising a carbon and energy source (e.g., glucose), a source of inorganic nitrogen (e.g., ammonium sulfate), a phosphate salt (e.g., potassium phosphate), an alkali metal (e.g., calcium) an alkaline earth metal (e.g., magnesium), transition metal (e.g., iron), an antifoam agent, a chelating agent and biotin.

Shirai et al., disclose a culture medium comprising citric acid, glucose, ammonium sulfate, biotin, potassium phosphate, calcium chloride, sodium chloride, copper, iron, zinc and other trace elements and an antifoam (Column 5, Lines 65-68; Column 6, Lines 1-32 and Column 8, Table 3).

Shirai et al's medium is comprised of an organic carbon/energy source (e.g., glucose), an inorganic nitrogen source e.g., ammonium sulfate), an alkali metal (e.g., calcium and sodium) an alkaline earth metal (e.g., magnesium), a transition metal (e.g., iron), potassium phosphate, a chelant (citric acid), an antifoam (Column 6, Line 31) and a vitamin (biotin, See, Column 8, Table 3). Shirai et al., further disclose that the culture medium disclosed in Table 3 was dispensed in a pre-sterilized 500-mL conical flask (Column 8, Lines 8-10).

Shirai et al., however do not disclose that their culture medium is free of bacteria or particulate material.

Pelczar et al., disclose that steps in preparation of a culture medium are: (i) dissolution of each ingredient in an appropriate quantity of water, (ii) verification and if necessary, adjustment of pH, (iii) dispensing the medium in an appropriate container, and (iv) sterilization in an autoclave (Page 110, Lines 26-27 to Page 111, Lines 1-7). Pelczar et al., further disclose that heat provided as saturated steam under pressure is the most dependable form of sterilization to kill microorganisms and the apparatus that can accomplish this is the autoclave (Page 428, Lines 16-29).

It would have been obvious to a person of ordinary skill in the art at the time the instantly claimed invention was made to prepare the culture medium of Shirai et al according to the teachings of Pelczar et al., because Shirai et al., teach a culture medium composition comprising the same components (i.e., a carbon/energy source, an inorganic nitrogen source, an alkali metal, an alkaline earth metal, a transition metal, potassium phosphate, a chelant, an antifoam (Column 6, Line 31) and biotin) as are recited in the instantly claimed invention, and Pelczar et al., teach that all the components of a culture medium should be dissolved in water and autoclaved to kill bacteria after the prepared medium has been dispensed in an appropriate container (Page 110, Lines 26-27 to Page 111, Lines 1-7; Page 428, Lines 16-29).

One having ordinary skill in the art would have been motivated to modify the preparation of the culture medium that Shirai et al disclose according to the teachings of Pelczar et al., because Shirai et al disclose a culture medium comprising a carbon/energy source, an inorganic nitrogen source, an alkali metal, an alkaline earth metal, a transition metal, potassium phosphate, a chelant, an antifoam and biotin (Column 6, Line 31; Column 8, Table 3); and Pelczar et al's teachings clearly imply that preparing the culture medium

according to the steps that Pelczar et al., have outlined (Page 110, Lines 26-27 to Page 111, Lines 1-7; Page 428, Lines 16-29) the said culture medium will be free of particulate material and bacteria because according to Pelczatr et al., each component of the culture medium should be dissolved and upon autoclaving the said culture medium, any microorganism (i.e., bacteria) present in the culture medium prior to it being autoclaved will be killed.

Based on the teachings of above cited prior art references that a culture medium comprising a carbon/energy source, an inorganic nitrogen source, an alkali metal, an alkaline earth metal, a transition metal, potassium phosphate, a chelant, an antifoam and biotin (Shirai et al., Column 6, Line 31; Column 8, Table 3) when prepared in steps that each component of the culture medium is dissolved in appropriate quantity of water and the complete medium after adjustment of pH is dispensed in an appropriate container and subsequently autoclaved to obtain a particulate and bacteria free culture medium (Page 110, Lines 26-27 to Page 111, Lines 1-7; Page 428, Lines 16-29), an artisan of ordinary skill would have had a reasonable expectation that a combination of all these teachings would result into a bacteria and particulate free culture medium. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

Thus, the claimed invention as a whole was clearly *prima facie* obvious under 35 U.S.C. § 103 (a), especially in the absence of sufficient, clear, and convincing evidence to the contrary.

12. In response to this rejection, applicants argue that Shirai et al., do not anticipate claims 1-12 since the culture medium composition that they have disclosed are "merely optional".

Applicants' arguments regarding the prior art references have been fully considered but are not persuasive. Claims 1-3, 6-7 and 10-12 are still anticipated by Shirai et al., for the reasons stated below.

Shirai et al., disclose a culture medium comprising glucose, ammonium sulfate, potassium phosphate, calcium chloride, sodium chloride, copper, iron, zinc and biotin (See, Column 7, Table 3).

Argue, further the applicants that the examiner has made a speculative statement that "... is common knowledge in the microbiological art that a culture medium is sterilized prior to inoculating it with a particular organism" but the Examiner has failed to provide any referenced statement and even if the examiner could provide the proof that the culture media are sterilized without exception, it must be shown that this sterilization step also results in the removal of all particulate material.

Applicants' above arguments regarding the sterilization of culture media and media being free of particulate material have been fully considered but are not persuasive for the reasons given below.

The fact that the culture media are sterilized to kill bacteria is well known in the microbiological art is evidenced by the citation in a Microbiology textbook (See Pelczar et al., 1977, Pages 111, Lines 1-7 and Pages 428, Line 25-34 and Page 429 Lines 7-10, after Figure 22-3). Furthermore, the biotin component in Shirai et al's disclosure is dissolved in the culture medium, and therefore, it is inherently free of particulate material because it is present in the culture medium in the same form as is disclosed in the claimed invention.

Thus, all the nutritional components (including biotin) of culture medium are in non-particulate form and free of bacterial or microbial cells until the culture medium is inoculated with a given microorganism (bacterium). Furthermore, Shirai et al., have disclosed a chelating agent and antifoam as components of their culture composition (Column 6, Lines 1 and 31), even though some of these components may not be required under certain circumstances (e.g., antifoam will not be required when the cells are cultivated on a solid medium containing agar, See, Column 7, Table 2).


Thus, Shirai et al., disclose a culture medium comprising an organic carbon/energy source (glucose), an inorganic nitrogen source (ammonium sulfate), a source of phosphate (potassium phosphate), a metal (calcium chloride), trace metals (e.g., zinc), a chelant (citric acid), antifoam, and particulate and bacteria free biotin.

13. No Claims are allowed.


14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6:00 P. M. (Eastern Standard Time or Eastern Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


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Patent Examiner
Art Unit 1651
(703) 605-1196

August 21, 2002


LEON B. LANKFORD, JR.
PRIMARY EXAMINER